



Mail Stop Amendment
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wai-Chiu So, et al.

Examiner: LANDAU, Sharmila

Serial No.: 09/673,872

Art Unit: 1616

Filed: December 4, 2000

Conf. No.: 5826

For: PHARMACEUTICAL COMPOSITION

DECLARATION UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Barry Hunt, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true and statements made on information or belief are believed to be true.
2. I am currently employed by Stiefel Research Australia Pty. Ltd., the assignee of the subject application.
3. I am a formulation Scientist and have been in pharmaceutical research since 1972. I have been doing formulation research and development for the last 35 years. My *Curriculum Vitae* is attached as Exhibit A.
4. I have reviewed and analyzed the above-referenced patent application, and I am familiar with the contents therein. In addition, I have read the Office Action dated June 11, 2007, received in the present case, and I have reviewed the references cited therein by the Examiner.
5. It is my understanding that the Examiner has rejected claims 1-3, 6, 8, 12, 13, 15-16, 19-21, 23-24, 26-29, 112-114, 118-119, 121-128, 131-132, and 135-138 as allegedly being unpatentable over Peck et al. (PCT published application No: WO 88/01863) in view of Weiner et al. (WO 97/12602) or Yu et al. (EP0273202). Further, it is my understanding that the Examiner has rejected claims 14, 30-33, 36-44, and 133 as allegedly

being unpatentable over Peck et al. in view of Weiner et al. (WO 97/12602) or Yu et al. (EP0273202) respectively in further view of Uchikawa et al. (U.S. Patent No. 5,156,836). For the reasons set forth herein, the Examiner's concerns are overcome.

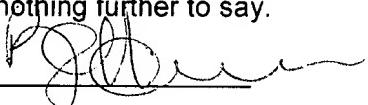
6. The compositions described in the prior art typically require a very high percentage (e.g., 30% to 50%) of a polyhydric alcohol in order to improve the solubility of a high concentration (e.g., 5%) of minoxidil. However, such high amounts of polyhydric alcohol are not pharmaceutically or cosmetically elegant, may be unacceptable to the consumer, and may cause local irritation and hypersensitivity upon application to the scalp (see, page 1, lines 11-21, of the instant application).
7. Peck et al. teaches minoxidil compositions containing a polyhydric alcohol selected from propylene glycol, a glycol, and/or 1,3 butylene glycol. See page 2; the composition described on page 3, paragraph 8; compositions (a)-(g); and the exemplified compositions.
8. Although Peck et al. exemplifies compositions containing no more than 5% minoxidil, such compositions contain a very high percentage (i.e., 50%) of a polyhydric alcohol. For example, compositions (e) and (f) each contain 5.0% minoxidil and 50.0% propylene glycol; the compositions of Examples 5 and 6 each contain 5.0% minoxidil and 50.0% propylene glycol; and the compositions of claims 13 and 14 each contain 5.0% minoxidil and 50.0% propylene glycol. As such, similar to other compositions described in the prior art, the compositions exemplified in Peck et al. contain a very high percentage (i.e., 50%) of a polyhydric alcohol in order to improve the solubility of a high concentration (i.e., 5%) of minoxidil.
9. In stark contrast, the present invention teaches compositions comprising at least 5% by weight of minoxidil or a pharmaceutically acceptable salt thereof, an acid to substantially solubilize the active agent, a solvent selected from water and a lower alcohol, and a co-solvent selected from aromatic alcohols and polyhydric alcohol, wherein when the co-solvent comprises one or more polyhydric alcohols, the one or more polyhydric alcohols are present in an amount of *less than 10%* by weight. As a result, the amount of polyhydric alcohol in the compositions of the present invention is at least 5-fold lower than the amount found in the high (i.e., at least 5%) minoxidil compositions described in Peck et al. In particular, the compositions of the present invention contain substantially lower concentrations of polyhydric alcohol because the acid component advantageously improves the solubility of the minoxidil. As such, the use

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of an acid to solubilize at least 5% of minoxidil, instead of the use of a very high percentage of a polyhydric alcohol as exemplified by Peck et al., circumvents the above-described disadvantages associated with a very high polyhydric alcohol concentration.

10. For these reasons, I believe that the present invention is not rendered obvious by Peck et al.

The declarant has nothing further to say.



Barry Hunt

Date

1 Nov 2007



Resumé for

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Summary:

I have always been interested in science, especially chemistry. I enjoy developing and working with products such as cosmetics and pharmaceuticals. I enjoy working as part of a team but can function and focus alone if required.

My experience working in the fields of food analysis and animal disease diagnosis (prior to my interest in cosmetics and pharmaceuticals) has given me a broad knowledge of analytical methods and an understanding of biology and physiology that have been very useful in my current occupation.

Employment History

Current position

Senior Formulation Scientist,
Stiefel Research Australia Pty Ltd
Previously Connetics Australia Pty Ltd
Previously Soltec Research Pty Ltd
Rowville, Victoria, Australia
1998 - current

Previous Positions

Development Chemist
Ensign Laboratories Pty Ltd
Mulgrave, Victoria, Australia
1972 - 1998

Laboratory Technician
Reckitt and Colman Food Division
Research Laboratories/Analytical division
Norwich, England
1968 - 1971

Laboratory Technician (Scientific Assistant)
Veterinary Investigation Centre
Ministry of Agriculture, Fisheries and Food,
Norwich, England.
1964 - 1968

Education

Received my tertiary education in chemistry at Caulfield Technical College (now Monash University, Caulfield Campus) in Melbourne.

After leaving school in England, I studied chemistry at a Technical College (Norwich City College), to Grad RIC part I level.

The combination of my studies in England and Australia qualifies me as a corporate (full) member of the Royal Australian Chemical Institute (RACI).

Professional Societies

Royal Australian Chemical Institute

This is the qualifying body for chemists in Australia.

An active member of the RACI after joining in 1975. Involved in some of the groups (e.g. Organic Chemistry, Pharmaceutical Sciences), and have had a paper on Cosmetics published in the official journal, "Chemistry in Australia".

Australian Society of Cosmetic Chemists

Became interested in the Australian Society of Cosmetic Chemists (ASCC), which was very relevant to my earlier work at Ensign Laboratories and still relevant to my current work. Although the projects at Connetics Corporation have been focussed more on pharmaceuticals, the basic principles of cosmetic formulation still apply in many ways. This cosmetic connection will become more important in the context of the Stiefel range of products. Have been active on ASCC committees and the Council, and served as President of the ASCC for two years. I am now a life member.

Society of Cosmetic Scientists

Joined this UK organisation in 1985. Have not attended any functions but find their newsletters and their publication, the International Journal of Cosmetic Science, very useful.